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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,971	09/24/2003	Nathan A. Winslow	5490-000337	4885

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,971

Applicant(s)

WINSLOW, NATHAN A.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-15,17,19-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-15,17,19-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/23/2006.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 13, and 19 in the reply filed on September 18, 2006 is acknowledged.
2. Applicant's cancellation of claims 4, 16, 18, 23, and 25 in the reply filed on September 18, 2006 is acknowledged.

Claim Objections

3. Claim 13 is objected to because of the following informalities: (i) please substitute "coupled to bone extending" (see lines 4-5) with --coupled to bone, said stem extending--, and (ii) please substitute "arch said flange" (see line 8) with --arch, said flange--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Regarding claim 24, "said preparing step" (see line 1) lacks antecedent basis. This was addressed in the previous office action.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

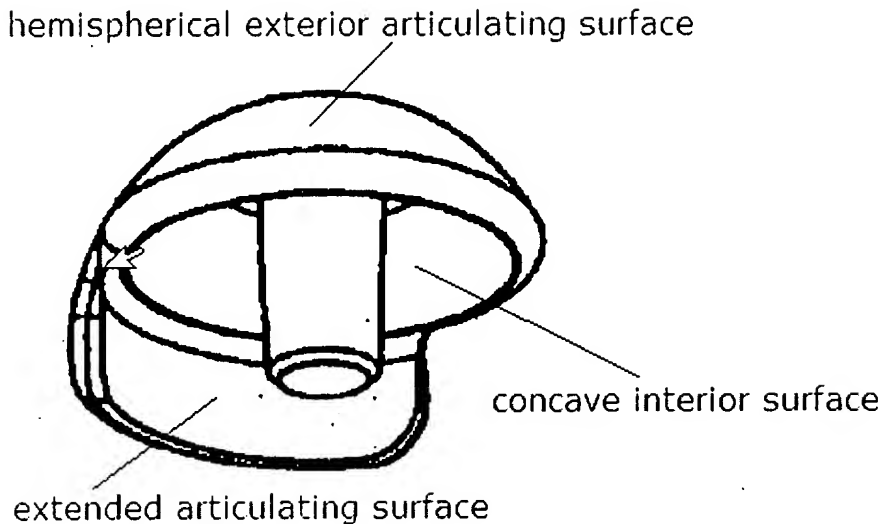
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3 and 6-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003).

Referring to Drawings 1-4, the BIOMET brochure disclose a resurfacing humeral implant comprising:

- (i) A hemispherical exterior articulating surface;
- (ii) A concave interior surface opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary) straight, tapered anchoring device (see drawings) having a textured outer surface (brochure disclosed it as a glass bead blast), said anchoring device extending from said interior surface; and
- (iv) An extended articulating surface protruding from a portion of said hemispherical exterior articulating surface. The second (i.e., lateral view) and fourth (i.e., main or fourth) drawings shows the extended articulating surface as comprising a "step".

Main (fourth) drawing of the BIOMET brochure shown below:



8. Claims 1-3, 5, 6, 8, 10, 12, 19, 20, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rambert et al. (FR 2 578 739; cited in Applicant's IDS).

Referring to Figures 1-3, Rambert et al. disclose a resurfacing humeral implant comprising:

- (i) A hemispherical exterior articulating surface (exterior surface of spherical cap 2);
- (ii) A concave interior surface (interior surface of spherical cap 2) opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary) straight, tapered anchoring device (anchoring pin 7 and/or bush 4) having a textured outer surface (threads or flutes of bush 4), said anchoring device extending from said interior surface; and
- (iv) A planar extended articulating surface (8) protruding from a portion of said hemispherical exterior articulating surface.

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9. Claims 1-3, 5, 6, 8-15, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Prybyla (US 6,045,582; cited in Applicant's IDS).

Referring to Figures 1-3, Prybyla discloses a resurfacing shoulder implant comprising:

- (i) A hemispherical exterior articulating surface (articulating surface 44 of head 14);
- (ii) A concave interior surface (**first interpretation:** recess 54; **second interpretation:** inner surface of extension skirt 50; **third interpretation:** recess 54 + inner surface of extension skirt 50) opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary) straight, tapered anchoring device (stem 12) having a textured outer surface (flutes 18), said anchoring device extending from undersurface 46; and
- (iv) A planar extended surface or flange (**first interpretation:** fin 34; **second interpretation:** extension skirt 50; **third interpretation:** fin 34 + extension skirt 50) protruding from a portion of said hemispherical exterior articulating surface. As seen in Figure 2, there are planar "V"-shaped inner surfaces formed on both sides of fin 34 that are configured to prevent/resist rotation of the prosthesis (see column 4, lines 53-57).

10. Claims 1-3, 6-13, 15, 17, 19-22, and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Long et al. (US PG Pub No 2004/0193277 A1).

Referring to Figures 7-23, Long et al. disclose a resurfacing humeral implant comprising:

- (i) A hemispherical exterior articulating surface (first body articulating surface 24);
- (ii) A concave interior surface (interior surface of first body 22) opposite said exterior articulating surface;

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- (iii) An integral (i.e., unitary) straight, tapered anchoring device (stem 36) having a textured outer surface (see blasted surface shown in Figure 10), said anchoring device extending from said interior surface; and
- (iv) An extended articulating surface (second body articulating surface 32 of second body 30) protruding from a portion of said hemispherical exterior articulating surface, and comprising a planar “V” shaped inner surface (see Figures 21 and 22). Long et al. also disclose the method as claimed in claims 19-22 and 24 (see pages 4-6).

11. Claims 19, 20, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the disclosure of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Referring to Figures 1-18, and the pictures on page 1, the brochure discloses a method for resurfacing a humeral head of an implant site, the method comprising:

- (i) Resurfacing the humeral head (see Figures 1-15; see entire document, particularly pages 3-7);
- (ii) Positioning a resurfacing humeral head implant (Copeland™ Humeral Resurfacing Head comprising a dome-shaped outer surface, a concave inner surface, and a tapered post having flutes and a blasted finish) on the resurfaced surface of the humeral head (see Figures 1-17; see entire document, particularly pages 3-8); and
- (iii) Positioning an extended articulating surface (i.e., the circumferential edge) of the resurfacing humeral head implant in a lateral region (a “lateral region” is broadly interpreted) so as to articulate with at least one of a bone and a ligament (see Figures 16 and 17; see entire document).

It should be noted that, from the claim language of independent claim 19, an arbitrary line or boundary distinguishes/defines the "extended articulating surface". It should also be noted that the circumferential edge of the implant "articulates with least one element of an coracoacromial arch" (see Figure 16). The brochure shows (see Figures 11-15) using a jig (i.e., a guide) and a trial implant.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003) in view of Pappas et al. (US 4,470,158).

The BIOMET brochure discloses the invention as claimed in claims 1-3 and 6-10. The BIOMET brochure did not particularly disclose said extended articulating surface as having "a planar "V" shaped inner surface". However, this is well known in the art. For example, Pappas et al. disclose joint prostheses comprising articulating surfaces having planar "V" shaped inner surfaces (**Figure 2**: inner surface of component 11; **Figures 37-41 and 63**: component/flange 100 comprises an extended articulating surface 106 having a planar "V" shaped inner surface; and **Figure 50**: inner surface of plate section 152) in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive

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stress on the bone (see column 6, lines 39-50 and lines 55-58; column 21, lines 8-15; and column 23, line 54 to column 24, line 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of joint prostheses comprising articulating surfaces having planar “V” shaped inner surfaces, as taught by Pappas et al., with the joint prosthesis shown in the BIOMET brochure, in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone.

NOTE: Looking to Applicants’ specification (see paragraphs 0022 and 0027), there is no criticality in the use of a “planar “V” shaped inner surface”. Furthermore, the Applicant admits in the present application that “the resection 52 may be of various other shapes or configurations” (see paragraph 0027).

14. Claims 11 and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Rambert et al. (FR 2 578 739; cited in Applicant’s IDS) in view of Pappas et al. (US 4,470,158).

Rambert et al. disclose the invention as claimed in claims 1-3 and 6-10. Rambert et al. did not particularly disclose said extended articulating surface as having “a planar “V” shaped inner surface”. However, this is well known in the art. For example, Pappas et al. disclose joint prostheses comprising articulating surfaces having planar “V” shaped inner surfaces (**Figure 2:** inner surface of component 11; **Figures 37-41 and 63:** component/flange 100 comprises an extended articulating surface 106 having a planar “V” shaped inner surface; and **Figure 50:** inner surface of plate section 152) in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone (see column 6, lines 39-50 and lines 55-58; column 21, lines 8-15; and column 23, line 54 to column

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24, line 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of joint prostheses comprising articulating surfaces having planar “V” shaped inner surfaces, as taught by Pappas et al., with the joint prosthesis of Rambert et al., in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone.

NOTE: Looking to Applicants’ specification (see paragraphs 0022 and 0027), there is no criticality in the use of a “planar “V” shaped inner surface”. Furthermore, the Applicant admits in the present application that “the resection 52 may be of various other shapes or configurations” (see paragraph 0027).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

November 1, 2006



David H. Willse
Primary Examiner